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December 21, 2018

VIA ELECTRONIC SUBMISSION TO www.regulations.gov

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-4185-P
PO Box 8013
Baltimore, MD 21244-8013

Re: CMS-4185-P: Medicare and Medicaid Programs: Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly, Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021; Policy and Technical Changes

To Whom It May Concern:

Cigna welcomes the opportunity to respond to the proposed rule that would make changes to the Medicare Advantage (MA) and Part D programs beginning in 2020 (CMS-4185-P). We appreciate the Centers for Medicare & Medicaid Services' (CMS or the Agency) efforts to improve the MA and Part D programs for beneficiaries by advancing access to care through greater use of telehealth services, increasing integration and coordination between Medicare and Medicaid for dual-eligible enrollees, and making improvements to the Star Ratings System to better measure performance and provide more meaningful quality information to beneficiaries.

We support several of the proposals, and believe they will strengthen the MA program by increasing access to vital services for MA enrollees and support plan efforts to improve quality for our members. Specifically, we welcome the proposed flexibility to offer additional telehealth services to enrollees, support the proposed path forward for increased integration of dual-eligible special needs plans (D-SNPs), and agree with the proposal to make Medicare Parts A and B claims data available to stand-alone prescription drug plans (PDPs). We have concerns about the provisions around provider and prescriber preclusion lists because they do not resolve ongoing questions about how the preclusion requirements will take effect in 2019.

This letter does not include comment on the Risk Adjustment Data Validation (RADV) audit provisions included in the proposed rule; we will address those provisions under separate cover in advance of the announced deadline of April 30, 2019. We appreciate CMS' recognition that the RADV issues discussed in the proposed rule are important to the MA program and welcome the Agency's decision to extend the comment period on those topics through April 30, 2019. We also welcome CMS' decision to disclose additional information and data regarding the empirical study described in the proposed rule. We hope the additional disclosures will respond to the issues raised by our prior correspondence,[1] and will be made in a sufficiently timely manner to enable stakeholders to evaluate and provide meaningful comments on the Agency's study.

[1] For reference, our prior correspondence is collected and resubmitted as Appendix A to these comments.

Cigna Corporation, together with its subsidiaries (either individually or collectively referred to as Cigna), is a global health services organization dedicated to helping people improve their health, well-being and sense of security. Our subsidiaries are major providers of medical, dental, disability, life and accident insurance, and related products and services. Worldwide, we offer peace of mind and a sense of security to our customers seeking protection for themselves and their families at critical points in their lives.

Cigna serves approximately 1.7 million people through our MA, Medicare Prescription Drug Program and Medicare Supplemental products. Our focus on this market has allowed us to develop a unique approach to health care coverage. We have a deep understanding of the needs and challenges facing both patients and physicians, and thus have developed an evolving collaborative model that provides greater access to high-quality preventive care for our customers while offering physicians what they need to deliver that care.

With that perspective in mind, we offer the following comments on the proposed rule:

Requirements for Medicare Advantage Plans offering Additional Telehealth Benefits

CMS proposes to implement provisions passed by Congress in early 2018 that allow MA plans to provide additional telehealth benefits to members, beyond those covered under Medicare Part B, and to consider the additional benefits as basic benefits when submitting bids. Under the CMS proposal, plans would have flexibility to determine which services would be appropriately furnished via telehealth, but could not require that beneficiaries access Medicare covered services via telehealth.

Cigna supports the additional flexibility to offer telehealth benefits provided by the Bipartisan Budget Act of 2018 (BBA) and CMS' proposed implementation as outlined in the rule. We have identified a number of areas where additional clarification is needed to ensure that plans are operationalizing the new flexibility appropriately:

Contracted Providers: We ask CMS to clarify the requirement that additional telehealth benefits be offered by contracted providers only. Would this allow a plan to contract with an entity such as Teledoc or MDLive, which offers telehealth consultations with physicians and providers, to be our exclusive telehealth provider for a selected set of services? How would a plan list such providers in the provider directory? Would the plan need to list every provider associated with a contracted service entity?

Also, we ask CMS to clarify how plans should address a case where a provider refers a member to a non-contracted telehealth provider. Would the plan be required to pay for such a claim?

Evidence of Coverage: CMS proposes that telehealth services must be identified in the Evidence of Coverage (EOC) and noted in provider directories made available to members. We ask that CMS be more specific about what information would need to be listed. We also ask CMS to provide model language for use in the EOC listing of telehealth benefits. For example, should cost sharing be specified by service, or in a separate section dedicated to telehealth services?

Network Adequacy: Cigna recommends that CMS allow plans to include telehealth providers to demonstrate network adequacy in certain circumstances. Specifically, we suggest that CMS allow the following to count toward network adequacy requirements: 1) mental and behavioral health providers offering services via

telehealth; 2) the availability of telehealth providers to members in rural or underserved areas; or 3) limited specialties that are shown to lack a sufficient number of providers in selected areas. Allowing telehealth providers to be counted for network adequacy purposes in these limited circumstances would increase access to MA in rural and underserved areas generally, and would improve access to critical mental and behavioral health services in particular. We do not believe it is necessary to count telehealth providers for network adequacy in other circumstances at this time.

Medicare Diabetes Prevention Program (MDPP): We ask for clarification on how the MDPP is to be treated for purposes of the proposed telehealth flexibility. Would plans be able to offer the MDPP benefit via telehealth beginning in 2020? We understand that CMS has previously rejected telehealth-only provisions of the MDPP. Cigna has had success using a digital diabetes prevention program in our commercially-insured population, and believe that the flexibility to offer a similar program to our MA members would increase access and improve completion and success rates for this population. Therefore, we urge CMS to specify that MA plans may offer the MDPP via telehealth in the future.

Diagnoses from Telehealth Encounters: Finally, we ask that CMS clarify how diagnoses identified through a telehealth service or encounter should be treated with respect to risk adjustment coding submissions to CMS. Should plans treat telehealth visits and services as in-person visits with respect to the identification of diagnosis codes? We ask CMS to instruct plans clearly on how to treat such diagnoses.

Dual Eligible Special Needs Plans Provisions

CMS proposes regulations to implement provisions in the BBA that require integration of Medicare and Medicaid benefits beginning in 2021 for D-SNPs. These regulations would create new expectations of D-SNPs to coordinate access to Medicaid services for dual-eligible enrollees and to report hospital and skilled nursing facility (SNF) discharges to state Medicaid agencies for at least a subset of enrollees, as defined by individual states. CMS also proposes requirements to create an integrated appeals and grievances systems for certain types of D-SNPs.

Cigna supports the requirements proposed for D-SNPs beginning in 2021. We agree with CMS' stated understanding of the BBA provisions, which allow for three types of D-SNPs to operate in 2021 and beyond: Fully-Integrated D-SNPs (FIDE-SNPs), D-SNPs that are part of a parent organization that also operates a Medicaid managed care plan in a state (HIDE-SNPs), and stand-alone D-SNPs that are not FIDE-SNPs or HIDE-SNPs, but actively assist enrollees in accessing and coordinating Medicaid services. We also support CMS' proposal to implement an integrated appeals and grievance process for beneficiaries enrolled in FIDE-SNPs and HIDE-SNPs.

A core principle of the MA program is that competition among private plans translates into higher quality and greater value for beneficiaries. Allowing the continued operation of all types of D-SNPs ensures that enrollees and taxpayers will continue to benefit from vigorous competition through access to greater supplemental benefits and services, along with lower cost sharing. Restricting that competition would reduce the value MA offers to these vulnerable beneficiaries, which we believe is preserved by allowing beneficiaries to proactively elect the benefit plan most appropriate for their health care needs.

As CMS moves forward in finalizing these provisions and considering any additional D-SNP integration requirements, we recommend the Agency prioritize the following goals:

- Provide flexibility for D-SNPs to accommodate reasonable state design differences (such as state-imposed variations in managed long-term care services and supports and behavioral health coverage, carve-outs and capitations);
- Reduce complexity for beneficiaries and minimize plan and state administrative burden, where possible, by building, refining or aligning existing processes; and
- Encourage and enable partnerships between states and D-SNPs, perhaps by requiring that states and plans submit a joint plan for achieving a mutually-agreed-upon level of integration, enrollment alignment, and timelines for meeting FIDE-SNP status or higher levels of integration where possible.

In addition, as CMS moves forward to finalize these rules, we ask CMS to provide clarification on several issues that will be important for successful implementation:

- **Coordination and Assistance**: CMS should provide more specific information about expectations that D-SNPs coordinate and assist enrollees in accessing Medicaid services, including accessing benefits or help in submitting grievances or appeals for Medicaid-covered services. We ask that CMS specify the range of activities D-SNPs would be expected to undertake as part of the required coordination and assistance.

- **Hospital/SNF Discharge Data Exchange**: While Cigna recognizes that states will implement the reporting requirements individually, we ask that CMS provide technical assistance and guidelines for how such reporting should be done. Standardization of data exchange and health information technology will contribute to the value of the data for benchmarking and quality improvement activities.

- **Defining "High-risk" Populations**: CMS proposes that states would define the population of dual-eligible enrollees for which D-SNPs would be required to report on hospital and SNF discharges. We ask that CMS provide guidance to plans and states on how high-risk populations should be defined.

We also ask CMS to undertake provider education about these new requirements as they move forward. The information that D-SNPs will report to states will only be as accurate or timely as the information they receive from providers. Prompt and complete claims submissions from hospitals and SNFs will enable states and Medicaid managed care plans to use the information received to integrate needed Medicaid benefits and services.

Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts

CMS proposes to establish a process for PDPs to request and receive Medicare Parts A and B claims data about plan enrollees, as required under the BBA. CMS outlines proposed permitted and prohibited uses of the data, along with a timeline for how and when PDPs would receive the data.

Cigna supports the proposed framework for providing access to the Parts A and B data, including the allowed and prohibited uses. We do, however, ask that CMS clarify how PDPs may use the data for fraud and abuse detection activities. Specifically, we believe that PDP sponsors should be allowed, on a retrospective basis, to use diagnosis information provided in the Parts A and B data to consider where use of selected Part D drugs is for medically accepted, Part D-eligible indications. Patterns of prescribing for non-medically accepted indications can be reviewed against information submitted to the plan as part of fraud and abuse detection. CMS should clarify that while PDPs may not use the Parts A and B data to change individual coverage determination decisions alone, they may review this data as part of an effective fraud and abuse detection program.

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

CMS proposes several changes to the way that measure cut-points are determined, with the goal of reducing the likelihood of large jumps in those cut-points, and corresponding rating thresholds, from year to year. Cigna appreciates CMS' efforts to provide greater stability to individual measure cut-points over time. We are generally supportive of the proposals outlined below, which would smooth the trajectory of change in cut-points over time and better account for outliers. However, we also believe that CMS should do more to prevent outliers from skewing measure cut-points and we offer some suggestions for additional steps the Agency should take.

Mean Resampling: In an effort to reduce the impact of outliers on measure cut-points determined via the clustering methodology, CMS proposes to randomly separate measure scores into 10 equal-sized groups. Clustering would be done 10 times, each time leaving one of the 10 groups out. The mean of the 10 runs would become the measure cut-point.

Cigna appreciates CMS' efforts to reduce the volatility of cut-points, which results from small plans experiencing large changes in scoring from year to year due to small numbers. The impact of such plans is especially important in the ratings of PDPs, because the population size is limited (49 PDPs received a Star rating for 2019).

We believe that mean resampling is a positive step forward as a way to reduce the impact of outliers on measure cut-points, but we believe CMS should do more. Specifically, we urge CMS to weight individual plan scores by enrollment to better reflect national beneficiary experience and further reduce the impact of small plans that may experience large changes in scoring from one year to the next due to small numbers. Using enrollment-weighted scores to determine cut-points would reduce the impact of small plan outliers on measure ratings, and more appropriately reflect the true experience and performance of the majority of MA enrollees.

We also ask that CMS provide additional information on the impact the proposed mean resampling would have on cut-points. For example, CMS should use data for 2019 ratings to conduct a simulation of measure cut-points using the proposed methodology, and make the simulation available to plans for evaluation.

Cut-point Guardrails: CMS proposes adding a bi-directional cap that restricts cut-point movement both above and below the prior year's cut-point by five percent for measures that have been included in Stars for at least three years. We are generally very supportive of CMS' efforts to better control and manage year-over-year variations, especially when driven by outliers.

As with the mean resampling, Cigna supports CMS' efforts to better account for large changes in cut-points, especially for measures that see large shifts from year to year, driven by outliers (*e.g.*, 2019 Comprehensive Medication Review rates). We support limiting increases in cut-points, but do not believe the limit should apply when cut-points decline. Plan consolidations, unanticipated changes in the marketplace, or clinical factors may result in declines in industry performance that should be reflected in ratings thresholds. Further, excluding downward guardrails will allow measures that currently have artificially high cut-points driven by performance outliers to return to parity more quickly. If CMS does implement bi-directional guardrails, we ask that the Agency consider how baseline cut-points are set to account for outlier influence on existing cut-points.

With regard to the proposed limit on movement of five percent, Cigna asks that CMS explain why five percent was chosen as the threshold. We also ask that CMS share information on unadjusted cut-points so plans can understand how performance standards will change in subsequent years.

Finally, we ask CMS to specify how measures that move to display due to significant specification changes would be treated when they return to active status. Will they be subject to the three-year prohibition when they return as active Star measures?

Controlling High Blood Pressure: CMS proposes moving the measure to display for 2020 and 2021 Star ratings due to specification changes introduced by the National Committee for Quality Assurance (NCQA). Cigna supports this proposal.

Medicare Plan Finder (MPF) Price Accuracy: CMS proposes maintaining the existing MPF Price Accuracy measure on display for 2020 and 2021 Star ratings while a new measure specification is developed. Cigna supports the proposal to keep the existing measure on display. However, we do not support the proposed changes to the measure going forward. We believe that measuring instances where a drug price paid at the point of sale exceeds the price reflected on the MPF by a penny is not a meaningful metric for beneficiaries or a meaningful measure of plan quality. Instead, we believe CMS should measure accuracy based on when a sale price exceeds the MPF price by more than five percent and the variance is at least $0.50.

Plan All-Cause Readmissions: CMS proposes moving the measure to display for 2021 and 2022 Star ratings due to NCQA specification changes. Cigna supports this proposal.

Timeliness Monitoring Project (TMP) Audit: CMS proposes adding an additional regulatory provision that would assign a 1-Star rating to the applicable appeals measure(s) if a contract fails to submit data requested as part of a TMP audit. Cigna supports the proposal because it would bring more consistency to Star ratings. We would like more information on the impact to Star ratings and Star cut-points for applicable measures if plans fail to submit TMP audit results prior to a regulatory provision being added for 2020. CMS should further consider adding a regulatory provision requiring that plans be provided with TMP audit results in advance of the First Plan Preview Period.

Review of Sponsors Data: CMS proposes to require that plan requests to the Independent Review Entity (IRE) or CMS to review appeals or complaints submitted to the Complaint Tracking Module (CTM) be received by June 30th each year. Re-openings would not be included in the proposed deadline.

While Cigna does agree that plans should make best efforts to be proactive in identifying and addressing data issues in advance of the plan preview period, we do not support a deadline of June 30th for plan requests to the IRE for review of appeals or complaint decisions. We recommend that the cut-off date be the end of the First Plan Preview Period. Removing a plans' ability to examine IRE data on decisions during the plan preview period negates the point of that exercise. Despite ongoing review of IRE decisions, a particular decision may only emerge as problematic during the plan preview period. For example, new information may emerge that changes a plan's interpretation of cases, such as TMP audit results or auditor feedback. Plans should be able to review the IRE decisions and challenge decisions that were incorrectly decided and result in inaccurate scores for affected measures.

Extreme and Uncontrollable Circumstances: CMS proposes codifying Extreme and Uncontrollable Circumstances that generally mirrors the disaster relief policy CMS adopted for the 2019 ratings. Cigna appreciates CMS' recognition that events such as natural disasters and other emergencies can affect beneficiaries' health care experience in ways that are beyond the control of the MA organization (MAO), and should be accounted for in Star ratings. We also appreciate CMS' effort to develop a consistent and stable methodology for adjusting ratings affected by such disasters. At the same time, we are concerned that codifying the methodology, particularly when it is still new, would prevent CMS from making adjustments as new circumstances arise. We recommend that CMS not finalize the methodology for Extreme and Uncontrollable Circumstances at this time. Instead, CMS should continue to assess the impact of the methodology over several years and different contingent circumstances to ensure that it is able to accommodate a range of emergency circumstances.

In addition, we urge CMS to consider the way ratings would be adjusted in cases where a local geographic area experiences multiple natural disasters or emergencies across several years. For example, in a case where a measure score for a given year is deemed to be unusable due to an emergency, CMS proposes to use the higher of the current year and the prior year score to measure performance. What if the prior year's score was itself affected by a natural disaster? We recommend that CMS clarify how measure scores would be determined under such circumstances.

Additional Suggestions for Incentivizing Improvement: CMS has expressed concern that plans have limited incentives to improve performance on measures that are put on the display page, since these measures are not included in the calculation of Star ratings. Cigna believes that CMS could create appropriate incentives for performance by allowing improvement in performance on display measures to be counted as part of the Improvement Measure for Star ratings.

We propose the addition of an upside-only incentive whereby points would be added to a contract's performance on the Health Plan Quality Improvement and Drug Plan Quality Improvement measures when significant year-over-year improvement occurs on qualifying display measures. This adjustment should only be calculated based on measures that have been on display for at least two consecutive years without material changes to the measure specifications during that time. We further recommend that the incremental upside adjustment to the Health Plan and Drug Plan Quality Improvement measures not be factored into cut-point development in order to maintain continued separation of Stars and display measures. We believe this extra focus on display measures would result in both improved beneficiary outcomes, and a better performance baseline when display measures move to active status, reducing the amount of year-over-year change in measure performance during the first few years.

<u>Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE</u>

CMS proposes changes to upcoming rules that require MA and Part D plans to cease paying providers or pharmacy claims from prescribers who are included on a Provider/Prescriber Preclusion List beginning in 2019. CMS states that the Provider/Prescriber Preclusion list ("the list") will become available on January 1, 2019. Under current rules, MAOs and Part D plans will be prohibited from making payments to precluded providers and prescribers as of April 1, 2019. In the rule, CMS proposes to postpone MA and Part D plan requirements regarding the list until January 1, 2020.

Cigna strongly supports implementation of the list as a means of safeguarding the Medicare program, reducing fraud, and protecting beneficiaries. We also support many of the changes to the Preclusion List proposed in the rule, but are concerned that multiple and varying effective dates will lead to confusion for beneficiaries, providers, prescribers, and plans, and could result in harm to beneficiaries who are unable to access medications or needed services. Further, we are concerned that without additional guidance from CMS that clearly specifies how plans are to implement the list, the intended positive outcomes of the effort will be overwhelmed by beneficiary confusion, provider and prescriber frustration, dissatisfaction with the MA and Part D program, and significant potential for beneficiary harm.

In light of the numerous changes to the Preclusion List proposed in this rule, along with the additional changes and uncertainty emanating from the recent HPMS guidance on precluded prescribers,[2] we urge CMS to delay implementation of the Preclusion List until it can fully address these concerns, and the many other issues raised by stakeholders. Assuming the issues and inconsistencies can be addressed in a meaningful way, we believe a January 1, 2020 effective date across the board for all requirements would be appropriate.

In the proposed rule, CMS expands upon and clarifies the "precluded provider" provisions finalized in the CY 2019 MA/Part D Policy & Technical Rule. In many cases, Cigna is supportive of these clarifications. Specifically, Cigna supports efforts by CMS to: (1) shorten the Preclusion List appeal timeframe from nine months to five months; (2) place providers and prescribers on the Preclusion List after their first level of appeal; and (3) prohibit beneficiary appeals of payment denials due to Preclusion List placement. These steps would protect beneficiaries and ensure precluded providers and prescribers do not continue to receive Medicare reimbursement, while reducing the administrative burden on plans.

However, rather than making corrections to the Preclusion List policies and delaying the effective date of all of the policies until January 1, 2020, CMS is proposing to take the unusual step of implementing the Preclusion List in a three-step, phased-in process. Such a disjointed roll-out could be extremely problematic for plans, providers, and beneficiaries. As we understand the framework being proposed, CMS would phase in the Preclusion List in the following timeframe: (1) beginning on January 1, 2019, the Preclusion List will go into effect *without* any of the proposed reforms introduced in this rule; (2) 60 days following publication of the final CY 2020 rule, Medicare plans will be required to implement the new consolidated appeals provisions; and (3) finally, any other changes made in the 2020 NPRM will not go into effect until January 1, 2020.

These multiple phases of implementation, with shifting policies and effective dates, will be harmful and confusing. Beneficiaries will face confusion as the rules under which their provider and/or prescriber may or may not be placed on the Preclusion List change throughout the benefit year. Likewise, they may be particularly confused as to whether they have appeal rights, with the issue not addressed for 2019 but with appeals then apparently not allowed as of 2020.

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[2] CMS, HPMS memo, "Preclusion List Requirements," November 2, 2018. Accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-Week1-Nov-1-2.html?DLPage=2&DLEntries=10&DLSort=1&DLSortDir=descending

Based on past experience since provider enrollment was first proposed in 2015, Cigna does not believe CMS' proposal to implement any of the Preclusion List requirements on January 1, 2019 is realistic. Implementing these requirements in the proposed manner will challenge Part D plan operations and cause potential harm to beneficiary access. CMS must provide clear guidance on how MA and Part D plans are expected to implement the requirements before moving to hold them accountable or expect beneficiaries, providers, or prescribers to understand the new rules. These operational issues include:

Prescriber Notice: We ask that CMS clarify whether Medicare plans are required to notify providers and prescribers of inclusion on the Preclusion List. The proposed rule states that a plan "must ensure that reasonable efforts are made to notify the prescriber," yet does not identify what these "reasonable efforts" are. What standard should plans follow?

Beneficiary Appeal Rights: In the proposed rule, CMS notes that it is updating the regulatory text to confirm that if payment is denied because the prescriber or provider is on the Preclusion List, the affected beneficiary would not have the right to appeal that denial. Cigna supports this clarification, but it raises several issues, including:

- Will enrollees be permitted to appeal the denial of a claim (due to a provider's placement on the Preclusion List) during CY 2019 given that beneficiary appeals were not addressed in the 2018 rule applicable to CY 2019? If so, how does CMS intend to notify beneficiaries of the change in policy for CY 2020?
- While we understand the beneficiary cannot appeal the provider's status of preclusion, we also assume that they cannot appeal the Medicare plan's denial of a claim. We would ask CMS to confirm this.
- We understand a beneficiary who received notice the provider was excluded but continued to use that provider could not appeal the denial of that claim, however, what about the beneficiary who for some reason did not receive the notice?
- Does CMS intend to add language to the notification letter advising the beneficiary that appeal rights will not apply when a claim is denied due to the precluded prescriber programs? We urge CMS to do so.

In light of the unanswered questions regarding implementation of the Preclusion List, and the fact that this proposed rule would make changes to the rules for implementation after the new requirements are scheduled to go into effect on January 1, 2019, Cigna strongly recommends that CMS delay implementation of the effective date until January 1, 2020. At a minimum, CMS should make clear that enforcement of the new requirements will not go into effect before 2020 and before CMS has released guidance that clarifies the operational issues discussed above.

We note that CMS has delayed implementation of the precluded provider and prescriber provisions several times in the past, and Cigna does not recommend further delay lightly. As stated earlier, we strongly support efforts to reduce fraud, waste and abuse, and believe the precluded provider and prescriber provisions would be a step forward. However, the existing guidance is insufficient to make the rules work for beneficiaries, providers, prescribers, or the Medicare program and the changes proposed for 2020 would only add to the confusion. Beyond setting a new effective date, CMS must commit to working with plans to identify and overcome operational challenges, and to do so on a timeline that allows for careful implementation of the new rules in advance of the effective date.

In summary, Cigna supports CMS' efforts to improve the MA and Part D programs through increased use of telehealth, improvements to the Stars Rating System, and greater integration of Medicare and Medicaid services for dual-eligible enrollees. We have serious concerns with the implementation of the provider and prescriber preclusion lists, and urge CMS to work with MAOs and Part D sponsors to ensure the new requirements improve the integrity of the programs without causing harm to enrollees.

Thank you for your consideration of these comments.

Respectfully,

David Schwartz

Appendix A: Prior Correspondence on RADV Audit Provisions

November 5, 2018

Jonathan Smith, Senior Technical Advisor
Joanne Davis, Senior Analyst
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4185–P
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Baltimore, MD 21244–1850

Re: CMS–4185–P, Proposed Rule: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

Dear Mr. Smith and Ms. Davis:

You are listed as the contacts for further information in the proposed rule that the Centers for Medicare and Medicaid Services (CMS) released on October 26, 2018 and published in the Federal Register on November 1, 2018. *See* 83 Fed. Reg. 54,982. I write on behalf of Cigna Corporation, which provides health insurance coverage to hundreds of thousands of Americans as part of the Medicare Advantage (MA) program. As a participant in the MA program, Cigna has a direct interest in the proposed rule.

Cigna values its partnership with CMS. Both CMS and Cigna have a shared commitment to the MA program. We believe that our shared commitment to the program has contributed in important ways to its success.

Because of that shared commitment, Cigna has repeatedly called on CMS to work with it and other stakeholders in addressing the issue of RADV extrapolation and a fee for service adjuster. Unfortunately, the proposed rule was not the product of that kind of cooperative, collaborative process. Cigna hopes that the process, going forward, can be improved to reflect a more cooperative, collaborative approach.

In that regard, it will be important that Cigna and other stakeholders have a meaningful opportunity to submit comments on the proposed rule. At present, however, Cigna and other stakeholders are unable to do so because CMS has failed to release the data and analysis upon which it relied in issuing the proposed rule.

The need for a meaningful opportunity to comment could not be more important here. In a sharp reversal of its prior policy CMS proposes "[t]o establish that CMS would use extrapolation in RADV contract-level audits," retroactively to payment year 2011, and without a fee-for-service (FFS) Adjuster. 83 Fed. Reg. at 54,984.

The proposed rule purports to rely, among other things, on various data and analyses that CMS asserts supports its position. Much of this information, however, is either undisclosed or only incompletely disclosed. For example, CMS has not adequately disclosed or explained:

- The "FFS data" from "the 2004–2005 file used for model calibration" (*see* Tech. App'x 5);
- The "MA sample" consisting of the "two million records that were sampled from the 2011 overpayment run (*see* Tech. App'x 5);
- The "sample of FFS claims and associated medical records" that were collected from the (CERT) audit" (*see* Tech. App'x 6);
- The "subset of 8,630 unique claims" from the CERT data used "for a RADV-like medical record review" (*see* Tech. App'x 6);
- The "HCCs mapped from diagnoses on the claims" from the CERT data used for the "RADV-like medical record review" (*see* Tech. App'x 6);
- The calculation of the "average number of underlying claims" per beneficiary in the 2004–2005 fee-for-service dataset (*see* Tech. App'x 9, table 2b);
- The bases for CMS's conclusion that each claim has an "independent" and equal probability of being unsupported (*see* Tech. App'x 9);
- The "estimate [of] a proxy for the CMS-HCC model on the original uncorrected dataset and estimate [of] the original factors" (*see* Tech. App'x 13);
- The application of "these original factors to the MA sample" and the resulting estimate of the "original risk scores for the uncorrected calibrating dataset" (*see* Tech. App'x 13);
- The "simulation[s] calculating 50 cases of the impact analysis" (*see* Tech. App'x 15);
- The results from each such simulation, including the "50 independent corrected FFS data files," the 50 "re-calibrat[ions of] the CMS-HCC model," the 50 "re-normaliz[ations of] a new set of risk scores," and the 50 "average[s] of the percentage difference in risk score" from the original score (*see* Tech. App'x 15–16);
- Other data and analysis CMS considered in undertaking its review; and
- Communications, reports, or other information received or exchanged with third parties, including consultants, that CMS considered or relied upon in conducting its analysis.

These are just examples and are not an exhaustive listing of all of the undisclosed data and analysis.

We urge CMS to immediately make publicly available *all* of the data, studies, and technical analyses underlying the proposal, as required by the Administrative Procedure Act (APA). "Under APA notice and comment requirements, '[a]mong the information that must be revealed for public evaluation are the 'technical studies and data' upon which the agency relies [in its rulemaking].'" *Am. Radio Relay League,*

Inc. v. FCC, 524 F.3d 227, 236 (D.C. Cir. 2008) (alterations in original). "[I]n order to allow for useful criticism, it is especially important for the agency to identify and make available *technical studies and data* that it has employed in reaching the decisions to propose particular rules." *Id.* (quoting *Conn. Light & Power Co. v. NRC,* 673 F.2d 525, 530 (D.C. Cir. 1982)). Indeed, unless commenters are able to review and digest this information and assess the agency's use thereof, "useful criticism" is impossible. *See id.* That is true especially where, as here, the agency's proposal incorporates complex technical and statistical analyses: "Public notice and comment regarding relied-upon technical analysis … are '[t]he safety valves in the use of … sophisticated methodology.'" *Id.* (quoting *Sierra Club v. Costle*, 657 F.2d 298, 334, 397–98 & n.484 (D.C. Cir. 1981)); *see also Engine Mfrs. Ass'n v. EPA*, 20 F.3d 1177, 1182 (D.C. Cir. 1994) (an agency must make public the "basis for … key assertions" in its analysis).

CMS's failure to release the required data and analysis has already prejudiced Cigna's and other stakeholders' ability to comment on the proposed rule, given the complexity of CMS's analysis and the short time frame provided to respond to the proposed rule. Release of this information is necessary to "ensure that [CMS's] regulations are tested through exposure to public comment, [ ] afford affected parties an opportunity to present comment and evidence to support their positions, and thereby [ ] enhance the quality of judicial review." *Am. Radio Relay League*, 524 F.3d at 236. It is also required by law. *See id.* (agency "failed to comply with the APA by not disclosing in full certain studies by its staff upon which [it] relied in promulgating the rule"). We ask that CMS immediately release to the public all of the data, studies, and analyses on which the proposal relies.

Please do not hesitate to contact me if you have any questions regarding this request.

Sincerely,

William A. Sarraille

cc: Janice Hoffman, Office of the General Counsel,
Department of Health & Human Services

November 27, 2018

VIA EMAIL AND OVERNIGHT MAIL

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Re: CMS-4185-P, Proposed Rule: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

Dear Mr. Smith and Ms. Davis:

I am writing on behalf of Cigna Corporation (Cigna) to follow up on my letter of November 5, 2018, concerning the Medicare Advantage (MA) and Part D proposed rule that the Centers for Medicare & Medicaid Services (CMS) published on November 1, 2018. *See* 83 Fed. Reg. 54,982. As explained in my prior letter, the Administrative Procedure Act (APA) requires that Cigna and other stakeholders have a meaningful opportunity to submit comments on the proposed rule. That can only occur if Cigna and others have access to the data, methodology, assumptions, and analysis upon which CMS relied in issuing the proposed rule.

My colleague and I spoke with your colleagues in the Office of General Counsel, copied below, on November 19, 2018. We are grateful for their willingness to discuss our client's serious concerns about the access issue. We discussed in that call the possibility of a joint policy and legal meeting to potentially continue the discussion. We believe that a further, substantive discussion would be beneficial, and we are available to meet at your convenience.

In the telephone call, we also discussed this supplementary letter, which your colleagues thought might be helpful. We discussed the following topics: (1) additional concerns that have arisen as Cigna has attempted to analyze the proposed rule; (2) the mechanisms by which the requested information, to the extent that it includes Protected Health Information (PHI) within the meaning of the Health Information Portability and Accountability Act of 1996 (HIPAA), can be shared with Cigna and others; and (3) whether Cigna could prioritize its requests for access. I address each of these in turn.

First, Cigna's concerns about the level of access provided and the implications for the ability of our client and others to comment meaningfully have only increased since I first wrote to you. Specifically, Cigna has identified the following additional questions and issues that were not adequately answered or disclosed in the proposed rule:

- Did CMS develop a protocol or statistical analysis plan prior to conducting the study described in the proposed rule? It is well recognized that the risk of bias increases substantially if a study does not follow an advance protocol and/or statistical analysis plan. If investigators fail to specify how a study or analysis will proceed in advance, they can alter their methodologies in ways that affect the ultimate results. CMS therefore must specify whether a protocol or similar plan was developed in advance of the study discussed in the proposed rule and make any such protocol or plan publicly available.

- Did CMS combine data from multiple Comprehensive Error Rate Testing (CERT) audits? The Technical Appendix (TA) states that CMS analyzed CERT data "for CY 2008 dates of service." However, CERT audits do not appear to be organized by calendar year. CMS's website states that the 2009 CERT audit reviewed claims submitted between April 1, 2008 and March 31, 2009.[3] Claims from the first quarter of 2008 were, presumably, reviewed during a prior audit. CMS must disclose whether and how it consolidated data from multiple CERT audits, along with any analyses conducted to assess the impact of such consolidation. We note that the CERT methodologies were substantially strengthened between the 2008 and 2009 audits, which led to a sharp increase in the number of claims deemed to be improper payments based on incomplete or missing medical record documentation.[4]

- How did CMS create its subset of CERT data? The TA also indicates that CMS created "a subset of 8,630 unique claims." Although the TA describes "inclusion" criteria, it does not specify whether additional ***exclusion*** criteria were used to create the subset. For instance, CMS likely excluded claims classified by the CERT Contractor as "No Documentation Errors." CMS also may have excluded claims classified as "Insufficient Documentation Errors." CMS must disclose all exclusion criteria used to create its CERT data subset, and any analyses conducted to assess the impact of those criteria. We note that excluding claims where the provider failed to submit complete documentation would obviously bias the subset towards supported diagnoses.

- Which specific diagnosis codes were found to be discrepant in CMS's review of its CERT subset? The TA discloses HCC-level discrepancy rates at Table 2A, but not the specific diagnosis codes deemed to be discrepancies. Because most HCCs include multiple ICD-9

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[3] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports-Items/November2009CERTReport.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=descending

[4] *See* Improper Medicare Fee-For-Service Payments Report - November 2009, at 11-12.

codes, Cigna cannot review and comment meaningfully on the Agency's observed discrepancy rates without knowing which specific conditions were at issue.

- What analysis supports the Agency's decision to estimate "beneficiary-level" discrepancy rates? The Executive Summary (ES) describes, at footnote 8, a prior analysis of claim-level discrepancy rates in the FFS program. Documents obtained through the Freedom of Information Act (FOIA) indicate that the prior analysis was also conducted with a subset of CERT data, potentially the same subset described in connection with the proposed rule. However, the ES criticizes the prior analysis on the ground that it failed to estimate "beneficiary-level" discrepancy rates. CMS must disclose any analyses supporting that critique and/or the Agency's decision to exponentially reduce the observed, claim-level discrepancy rates by simply multiplying probabilities. We note that this is appears to be a results-driven change in methodology.

- CMS must disclose all data, results, and methodologies from its prior review of CERT data. The Agency's prior review of CERT data is centrally important to Cigna's ability (and that of other stakeholders) to assess and comment on the study described in the proposed rule. *See, e.g.*, *Ramapough Mt. Indians v. Babbitt*, No. 98-2136, 2000 U.S. Dist. LEXIS 14479, *15 (D.D.C. 2000) ("An agency acts arbitrarily and capriciously when it ignores studies and data in its own files."). Yet none of the data, methodologies, or results from that prior review have been disclosed. As a result, Cigna and other stakeholders cannot evaluate CMS's assertions, including the highly suspect claim that the prior review "did not analyze the effect of FFS diagnosis error on the CMS-HCC model." ES at 4 n.8. We note that FOIA documents describe the prior review as an effort to "estimate[] how much higher [a] plan's payment would be if the model had been built using perfect data."

- CMS must fully disclose the methodologies for the simulations described in the proposed rule. The proposed rule describes "fifty simulations" based on estimates of beneficiary-level error rates. Neither the ES nor the TA, clearly describes how the simulations were run. This information must be provided before Cigna and other stakeholders can comment meaningfully on the proposed rule.

- CMS must disclose the recalculated coefficients resulting from the simulations described in the proposed rule. The proposed rule indicates that CMS recalculated the HCC risk score coefficients 50 times based on random deletions of HCCs at the estimated beneficiary-level discrepancy rates. None of the resulting coefficients have been disclosed. Disclosure of the simulated coefficients is essential to enable Cigna and other stakeholders to evaluate and respond to the Proposed Rule.

- CMS must disclose its normalization methodology: The TA describes a process by which CMS developed new coefficients generated from the "simulated corrected data." TA at 13. The TA then states: "In the next step, we take the new coefficients and apply them on the original FFS data set, normalizing a new set of relative factors to one." *Id.* Were the new coefficients normalized to 1.0 using the "corrected data" from which they were generated or the original FFS data that still contains the FFS diagnoses later removed to

generate the "simulated corrected data"? Please describe in detail how CMS conducted the normalization. This is an important step of CMS's methodology and must be addressed before Cigna and other stakeholders can comment meaningfully on the proposed rule.

- CMS must disclose how the "MA Sample" was created. The TA states that each time corrected HCC coefficients were simulated, the coefficients were "applied to the beneficiary profiles in the MA sample." The TA further states that the MA sample was created from "the 2011 overpayment run." CMS must disclose whether the MA sample reflects beneficiary profiles before or after retractions were applied. CMS also must disclose any and all inclusion or exclusion criteria used to create the MA sample.

Second, there are, in our view, multiple avenues under HIPAA to release the information at issue to Cigna and other affected issuer stakeholders. As an initial matter, we do not agree that HIPAA is relevant to many of our requests. For instance, a full and fair disclosure of the Agency's assumptions and methodologies would not reveal any PHI.

As to disclosure of the underlying data and medical records, the most fundamental point is that, for the reasons outlined in my November 5 letter, CMS is required under the APA to release the information underlying its proposal to permit meaningful critique of the proposed rule. HIPAA regulations specifically state that covered entities may disclose PHI to the extent that such disclosures are required by law. 45 C.F.R. § 164.512(a).

CMS also may disclose PHI for payment purposes. 45 C.F.R. § 164.502(a)(1)(ii); *id.* § 164.506(c)(3). The proposed rule is, in relevant part, a payment rule, as the presence or absence of a fee-for-service adjuster has a direct effect on payment. *See, e.g.*, 83 Fed. Reg. at 55038 ("We stated that the FFS Adjuster would calculate a permissible level of payment error (for example, a percentage of the total payments made on an MA contract in a given year) and limit RADV audit recovery to payment errors above that level."). Because Cigna is itself a covered entity and would use the information for purposes of helping to determine appropriate payments (and to help identify potential overpayments), the disclosure of the information by CMS to Cigna is permissible under HIPAA.

HIPAA also permits the disclosure of PHI for research purposes. *See, e.g.*, 45 C.F.R. § 164.512(i)(1). Cigna and others wish to conduct research on the study reported in the proposed rule. That research is permitted under the applicable regulations. *See id.*

Finally, while fully de-identified data would not provide Cigna and others the data elements required to review and comment meaningfully on CMS's proposal, CMS could disclose the necessary information pursuant to HIPAA's expert determination de-identification methodology, provided that sufficient information is retained to permit meaningful evaluation of the analyses. 45 C.F.R. § 164.514(b)(1).

Third, with respect to the question of prioritization, we stated during the telephone call on November 19 that this misses the point. To meaningfully comment on the proposed rule, Cigna needs to recreate the model that CMS advances. Without all of the data, analysis, assumptions, and methodology elements used by CMS, Cigna cannot evaluate the study described in the proposed rule. Comment will

necessarily and inappropriately be restricted if the study described in the proposed rule is not fully disclosed. *See, e.g.*, *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008); *Engine Mfrs. Ass'n v. E.P.A.*, 20 F.3d 1177, 1182 (D.C. Cir. 1994); *see also Nat'l Parks Conservation Ass'n v. EPA*, 803 F.3d 151, 167 (3d Cir. 2015) ("[W]e, as a reviewing court, need an agency to show its work before we can accept its conclusions.")

Since we understand that CMS requires additional time to consider disclosure of the requested information, Cigna asks that CMS extend the comment period on the proposed rule. An extension is necessary so that Cigna can obtain access to the information with sufficient time to permit it to review and comment on the proposed rule. As indicated in my November 5 letter, we believe that the failure to provide access to the missing data, analysis, and other information has already prejudiced Cigna and other stakeholders.

We would be happy to discuss our concerns further, and we hope the Agency would meet with us, as is traditionally the case during pending rules. It would be unfortunate if CMS would break from its settled practice and, in the case of this extremely important rule, refuse to meet with interested stakeholders like Cigna.

We look forward to your response.

Sincerely,

W. Sarraille

William A. Sarraille

cc: Janice Hoffman, Office of the General Counsel, Department of Health & Human Services
Susan Lyons, Office of the General Counsel, Department of Health & Human Services
Sean Griffin, Sidley Austin LLP